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Animal and Plant Health Inspection Service

Subcutaneous Vaccination of Wild, Free-ranging Bison in the Greater Yellowstone Area

Environmental Assessment

November 2003

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I. Purpose and Need of Proposed Action

A. Purpose and Background

1. Mission Related to Purpose and Need

The mission of the U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) is to protect and improve the health, quality, and marketability of our Nation's animals by preventing, controlling, and/or eliminating animal diseases and monitoring and promoting animal health and productivity (USDA, APHIS, VS, 2003).

2. Brucellosis: The Disease

Brucellosis is a serious disease affecting the health and productivity of cattle, bison, and elk. APHIS has worked for years to control and eliminate this disease from domestic and wild, free-ranging herds. These efforts have been successful in the domestic herds in the Greater Yellowstone Area (GYA). The vaccination of free-ranging bison in the GYA will serve to reduce the risk of brucellosis transmission from bison to cattle, while conserving free-ranging bison.

Brucellosis is a contagious disease caused by *Brucella* bacteria. It can infect cattle, bison, elk, other animals, and humans. In cattle, bison, and elk, the specific disease organism is *Brucella abortus*. In infected cattle and bison, the disease organism localizes in lymph nodes, reproductive organs, and/or the udder causing abortion in females and systemic effects in both males and females. Brucellosis is transmitted through contaminated and untreated milk and milk products and through direct contact with an infected, aborted fetus or calf; afterbirth; or other reproductive tract discharges. Cattle and bison are social animals that will sniff or lick a newborn calf, afterbirth, or aborted fetus. This type of behavior provides an avenue for the disease to spread if *Brucella* organisms are present.

Brucellosis is considered one of the most serious diseases of livestock. While its hallmark symptom is abortion, brucellosis also can result in decreased milk production, weight loss in animals, infertility, and lameness. In humans it causes generalized musculoskeletal aches and pains, fatigue, and mental depression and is accompanied by a fever that often spikes and then leaves only to return again. Thus, in humans, the disease is often called undulant fever. The symptoms can last for years.

3. Brucellosis Elimination Efforts

Efforts to eliminate brucellosis in cattle in the United States first began in 1934. At that time, 11.5% of cattle that were tested were considered infected with brucellosis. In 1954, the magnitude of the brucellosis program in terms of economics to the cattle industry and human health prompted Congress to appropriate funds for a comprehensive effort to eradicate brucellosis. This was a cooperative effort among the Federal Government, the States, and industry. In 1957, almost 124,000 brucellosis-infected cattle herds were disclosed.

As the program continued over the years, it was modified and improved to take advantage of new knowledge and technology. The most recent program standards are included in "Brucellosis Eradication: Uniform Methods and Rules" (UM&R), effective and published in the Federal Register February 1, 1998. It has taken a great deal of effort and diligence, but eradication of brucellosis from cattle and bison is near completion.

The regulations in 9 CFR Part 78 provide for a brucellosis classification system of States or areas of States, herds, and individual animals according to their status of brucellosis infection. States or parts of States are classified according to the rate of brucellosis infection in their livestock herds and the general effectiveness of their brucellosis eradication program. State classifications, starting with zero infection level, are Class Free, Class A, Class B, and Class C, with Class C designated as States or parts of States that do not meet the minimum standards and that may be placed under Federal quarantine. The most stringent restrictions are for States or areas of Class C designation. In the United States, a State must be free of brucellosis for a minimum of 1 year and fulfill certain surveillance criteria to be awarded brucellosis Class Free status. Currently, 48 States are brucellosis Class Free, including Idaho, Montana, and Wyoming; the remaining two States (Missouri and Texas) are designated as Class A. During 2002, two newly affected herds were disclosed, and during 2003, only one newly affected herd was disclosed. As of October 8, 2003, there are no affected herds. As is common near the end of a disease eradication program, occasionally an affected herd will be disclosed as the program moves toward total eradication. A State's ability to attain brucellosis-free status is economically important.

Clearly, great strides have been made in brucellosis eradication since the program first began in the 1930s. Since then, the cumulative cost to Federal and State governments and the cattle industry is estimated at greater than $3.5 billion (Cheville *et al.*, 1998), but cumulative benefits are believed to greatly exceed the cost.

4. Brucellosis in the GYA

The only known reservoir of *Brucella abortus* in the United States occurs in wild, free-ranging populations of bison and elk in the GYA, comprising areas of Idaho, Montana, and Wyoming. These wildlife populations serve as potential sources for brucellosis infection to animals in the GYA. It is estimated that 35 to 50% of the Yellowstone National Park (YNP) bison herd and 77% of the bison herd in the Jackson, Wyoming, area are seropositive and likely infected with brucellosis. The incidence of brucellosis in the GYA elk seems to be centered around the artificial winter feeding stations that have been established in Wyoming. The incidence of brucellosis in elk in the vicinity of the feeding stations is estimated to range from 17 to 40%. As distance from the feeding stations increases, the rate of brucellosis in elk in the GYA declines to 1 to 2% or less.

There has been a great deal of interest and discussion around the likelihood of transmission of brucellosis from wildlife populations to domestic livestock. The possibility of such a transmission was realized during the year 2002 when brucellosis was diagnosed in a cattle herd in Idaho. The epidemiologic investigation indicates that the infection was due to brucellosis-infected elk that had been fed on the same premises.

Elk and bison often leave the parks and refuges in the GYA and roam onto land that is or can be grazed by domestic livestock. The concern for transmission of brucellosis to cattle was one of the primary reasons for the establishment of the Greater Yellowstone Interagency Brucellosis Committee (GYIBC). The GYIBC is an interagency committee made up of Federal and State agencies with interests in the GYA. The GYIBC is dedicated to facilitating the development and implementation of brucellosis management plans for elk and bison in the GYA so as to protect and sustain the wild, free-ranging elk and bison populations and protect the economic viability of the livestock industry of the GYA. Specifically, GYIBC has issued a protocol with guidance on evaluating the safety and efficacy of vaccines against brucellosis in the GYA (GYIBC, 1998) (see Appendix A).

5. Bison Management in the GYA

The importance of wildlife in the GYA as a reservoir for brucellosis and a potential source of infection for cattle in the GYA has been widely recognized. Likewise, the existence of wild, free-ranging bison herds in the GYA is a natural resource of great importance. In an effort to resolve the potential conflict between disease management and natural resource preservation, the U.S. Department of the Interior's National Park Service and the State of Montana and their cooperators (including USDA) developed an Interagency Bison Management Plan (sometimes referred to as the Joint Bison

Management Plan) for theYNP bison herd. This plan was finalized after undergoing extensive analysis under the National Environmental Policy Act of 1969 (42 United States Code 4321 *et seq.*) (NEPA), which included the preparation of an Environmental Impact Statement (EIS) and a Record of Decision (ROD). The ROD was jointly recommended by the Administrator of APHIS, Chief of the U.S. Forest Service, and Director of the National Park Service. The ROD was then signed by the Secretaries of the Interior and Agriculture in December 2000. Likewise, the State of Montana prepared a similar Statement and Record of Decision. The Operating Procedures to be followed under the Interagency Bison Management Plan call for all management operations to be joint in nature, with the Montana Department of Livestock having the lead responsibility for management actions outside of YNP and the National Park Service having the lead for actions inside YNP. The other agencies will assist as needed. One of the disease management requirements of the Interagency Bison Management Plan agreed to by the agencies is for eligible bison to be vaccinated against brucellosis. Also, a plan is currently under development for the management of the elk and bison herds in the Jackson, Wyoming, area of the GYA. The plan may include vaccination of bison as an important component for disease management. This plan also will be scrutinized through the NEPA process.

As has been recognized in the Interagency Bison Management Plan for the YNP bison herd and agreed to by the agencies, vaccination is an obvious tool for use in managing and ultimately eliminating brucellosis in the GYA. The UM&R for brucellosis eradication, which provides procedures to be followed in the Cooperative State-Federal Brucellosis Eradication Program, contains procedures for vaccination of bison using either Strain 19 or RB51 vaccine (USDA, APHIS, VS, 1998). Vaccines are effective in reducing the spread of brucellosis by enhancing the immune-response capability to ward off an infection when the animal is exposed. They also can increase the level of bacteria required for an infective dose. The use of vaccines can decrease the frequency of abortion and, since abortion is the major mechanism for transmitting brucellosis, thereby reduce the potential for transmission.

Vaccination of elk is beyond the scope of this EA and will likely be considered when a cooperative comprehensive brucellosis elimination plan for the GYA is developed.

B. Need for This Environmental Assessment

Vaccination of bison in the GYA meets the criteria of a categorically excluded action under APHIS' NEPA Implementing Procedures (7 Code of Federal Regulations, Part 372). These regulations, in section 372.5(c), define categorically excluded actions as "(1) Routine measures such as . . . inoculations . . . employed by agency programs to pursue their missions and functions . . . provided that such use meets all of the following criteria . . . :

> (A) The use is localized or contained in areas where humans are not likely to be exposed, and is limited in terms of quantity, i.e., individualized dosages and remedies;
> (B) The use will not cause contaminants to enter water bodies, including wetlands;
> (C) The use does not adversely affect any federally protected species or critical habitat; and
> (D) The use does not cause bioaccumulation.
> (ii) Examples of routine measures include:
> (A) Inoculation or treatment of discrete herds of livestock or wildlife undertaken in contained areas (such as a barn or corral, . . .)."

Although an EA normally would not be required to initiate subcutaneous vaccination of bison in the GYA, APHIS is aware of the substantial interest among area residents, American Indians, and others concerning bison in the GYA. APHIS considered that undertaking an environmental review process would be in the best interests of those parties. Because of its expertise in animal diseases, APHIS has taken the lead in preparing this EA to facilitate any environmental review process that may need to be undertaken by a State or Federal agency prior to vaccination of bison in the GYA.

II. Alternatives Considered

The alternatives considered include (1) no action, (2) subcutaneous vaccination of wild, free-ranging bison with Strain 19, and (3) subcutaneous vaccination of wild, free-ranging bison with RB-51. However, other vaccination methods, such as remote vaccination, are being researched and may eventually be considered for use.

A. No Action

Under the no action alternative, there would be no vaccination of wild, free-ranging bison in the GYA. State and Federal agencies would take responsibility for, fund, and conduct all other bison management activities, including brucellosis-related actions such as testing, monitoring, and research, that are determined to be necessary in the GYA.

B. Subcutaneous Vaccination of Wild, Free-ranging Bison With Strain 19

Under this alternative, wild, free-ranging bison in the GYA would be vaccinated using Strain 19 vaccine. APHIS would assist in vaccination efforts. State and Federal agencies would take responsibility for, fund, and conduct all other bison management activities, including brucellosis-related actions such as testing, monitoring, and research, that are determined to be necessary in the GYA.

1. Background on Strain 19

General Description: Research by the U.S. Department of Agriculture and other parties has suggested that modified live vaccines are more effective than killed vaccines at producing immune responses to *Brucella abortus*. Therefore they are preferred to combat the bacteria that causes brucellosis. Strain 19 was a widely used modified live vaccine for induction of long-term protective immunity to infection by *Brucella abortus* in cattle and bison (USDA, APHIS, VS, undated). The Strain 19 vaccine has been researched and used in the United States and in other countries for more than 50 years to prevent *Brucella abortus* infection in cattle (Enright and Nicoletti, 1997).

Regulatory Status: Strain 19 was used in cattle and bison for many years; but it is no longer used in those species since the availability of RB51 (USDA, APHIS, VS, 2002a). While not licensed for general use in bison, the APHIS Administrator has approved the use of Strain 19 in bison under the provisions of 9 CFR Part 106.1.

Use in Brucellosis Eradication Program : Strain 19 is currently approved as one tool in the Brucellosis Eradication Program to combat *Brucella abortus*; but, in recent years, it is no longer used because of the availability of a newer vaccine (RB51), which has advantages over Strain 19, and some States no longer allow vaccination with Strain 19 as part of State eradication plans (USDA, APHIS, VS, 2002a). In addition, some published reports on controlled experiments (Davis *et*

al., 1991; and Davis, 1993) have questioned its efficacy in bison (see below).

Safety and Efficacy: The major complications of the Strain 19 vaccine are as follows: the antibodies produced by a vaccinated animal can interfere with the serologic tests that are designed for detection of the disease itself by causing false positive results if animals are tested for infection too soon after being vaccinated; because it is a modified live vaccine, Strain 19 is capable of producing the infection with the vaccine strain; and vaccination of pregnant cattle and bison with Strain 19 can cause abortions.

In order to obtain the best results and avoid the complications of the vaccine described above, female calves are vaccinated, preferably at 4–6 months of age. Strain 19 vaccine has been studied extensively in cattle where it is considered efficacious for preventing brucellosis (Enright and Nicoletti, 1997; USDA, APHIS, VS, 2001). Efficacy of Strain 19 in bison, however, remains unresolved. Davis *et al.* (1991) inoculated pregnant bison and most of them aborted. In the subsequent year, however, the vaccine did provide protection for two-thirds of the inoculated bison when compared to the controls. The only other controlled experiment on efficacy in bison was also done by Davis (1993). In this experiment, he subcutaneously vaccinated calves with Strain 19 at the standard dose rate. Data from this study indicate that calfhood vaccination of bison with Strain 19 at the recommended dose did not provide adequate protection. However, unpublished and anecdotal information indicates that Strain 19 is efficacious in bison vaccinated as calves older than 4 months in age.

2. Vaccination Procedure

When requested, USDA, APHIS, VS will cooperate with State agencies and Federal land management agencies in the management of bison in the GYA. Weed-free hay or other feed sources may be used to assist in the capture of nomadic bison. Once captured, bison will be separated, when feasible, into groups to minimize injuries from bulls or cows. A blood sample will be drawn from each bison to test for brucellosis. Testing will be conducted under the direction of a Federal- or State-employed veterinarian. Personnel involved in vaccination will be State-employed veterinarians or VS-approved veterinarians. Testing will consist of the use of one or more brucellosis serologic field test(s). Serostatus will be determined using procedures published in the UM&R and/or Code of Federal Regulations (CFR). While captured, each bison will be officially identified with an eartag and/or other permanent means of identification, and test records will be completed for each one.

Bison that test positive for brucellosis will be sent to slaughter or to a designated research facility. Only bison calves and nonpregnant yearlings that test serologically negative for antibodies to *B. abortus* will be inoculated with the *B. abortus* Strain 19 vaccine. A State or Federal veterinarian will inject the standard 2 milliliter (mL) dose containing at least 2.7 billion and not more than 10 billion colony-forming units of the vaccine under the skin in the neck or shoulder area of vaccine-eligible bison. Bison will be closely observed for a 15-minute minimum for anaphylactic reaction, a rare allergic hypersensitivity, to the inoculation. Any bison exhibiting reaction to the vaccine will be treated with epinephrine. After vaccination, seronegative bison calves and nonpregnant yearlings will be released into the wild, as permitted by agreed-upon bison management practices and plans. In addition to eartags (or other permanent markers), all released bison will receive an additional visual marking, such as clipping and/or dye-marking and backtags, to assist in the field identification of animals.

C. Subcutaneous Vaccination of Wild, Free-ranging Bison With Strain RB51

Under this alternative, wild, free-ranging bison in the GYA would be vaccinated using Strain RB51 vaccine. APHIS would assist in vaccination efforts. State and Federal agencies would take responsibility for, fund, and conduct all other bison management activities, including brucellosis-related actions such as testing, monitoring, and research, that are determined to be necessary in the GYA.

1. Background on RB51

General Description: RB51 is a modified live vaccine that can be used to impart long-term protective immunity to infection by *Brucella abortus* in cattle and bison. Considerable research on the RB51 vaccine has been conducted since its development in the early 1980s. A technical summary of the characteristics and studies conducted by USDA, Agricultural Research Service (ARS) on the RB51 vaccine is available from ARS in a separate document entitled "Brief Summary of *Brucella abortus* Strain RB51 Research Conducted with Bison at the National Animal Disease Center" (Olsen, 2001).

Regulatory Status: USDA, APHIS conditionally licensed RB51 for use in cattle in 1996 and granted a full license in March 2003 (CDC, 2003). While not licensed for general use in bison, the APHIS Administrator has approved the use of RB51 in bison under the provisions of 9 CFR Part 106.1.

Use in Brucellosis Eradication Program: RB51 has been approved for use in brucellosis eradication in cattle and bison. It is limited to use only by Federal, State, and/or accredited veterinarians.

Safety and Efficacy: Studies in cattle indicate that RB51 vaccine is efficacious. Although efficacy in bison has not been definitively determined, an efficacy study of RB51 vaccination in bison calves has also indicated that RB51 is efficacious in bison (Olsen, 2003). RB51 has been shown to be safe in nonpregnant bison (Olsen *et al.*, 1997; Olsen *et al.*, 1998; Olsen *et al.*, 1999; Roffe *et al.*, 1999; Elzer *et al.*, 1998). RB51 has some advantages over Strain 19 in that it appears to cause substantially fewer abortions and other post-vaccination reactions than Strain 19 when administered to pregnant female bison (USDA, APHIS, VS, 2002a). An additional major advantage of the RB51 vaccine over Strain 19 is that it produces a different antibody response in animals that does not interfere with standard tests for brucellosis infection (*i.e.*, no false positive tests due to vaccine) (USDA, APHIS, VS, 2002a).

2. Testing and Vaccination Procedure

When requested, USDA, APHIS, VS will cooperate with State agencies and Federal land management agencies in the management of bison in the GYA. Weed-free hay or other feed sources may be used to assist in the capture of nomadic bison. Once captured, bison will be separated, when feasible, into groups to minimize injuries from bulls or cows. A blood sample will be drawn from each bison to test for brucellosis. Testing will be conducted under the direction of a Federal- or State-employed veterinarian. Personnel involved in vaccination will be State-employed veterinarians or VS-approved veterinarians. Testing will consist of the use of one or more brucellosis serologic field test(s). Serostatus will be determined using procedures published in the UM&R and/or CFR. While captured, each bison will be officially identified with an eartag and/or other permanent means of identification, and test records will be completed for each one.

Bison that test positive for brucellosis will be sent to slaughter or to a designated research facility. Only bison calves and nonpregnant yearlings that test serologically negative for antibodies to *B. abortus* will be inoculated with the *B. abortus* strain RB51 vaccine. A State or Federal veterinarian will inject the standard 2 mL dose containing at least 10 billion and not more than 34 billion colony-forming units of the vaccine under the skin in the neck or shoulder area of vaccine-eligible bison. Bison will be closely observed for a 15-minute minimum for anaphylactic reaction, a rare allergic hypersensitivity, to the inoculation. Any bison exhibiting reaction to the vaccine will be

treated with epinephrine. After vaccination, seronegative bison calves and nonpregnant yearlings will be released into the wild, as permitted by agreed-upon bison management practices and plans. In addition to eartags (or other permanent markers), all released bison will receive an additional visual marking, such as clipping and/or dye-marking and backtags, to assist in the field identification of animals.

III. Environmental Consequences

A. No Action

Under the no action alternative, no vaccination of wild, free-ranging bison would take place in the GYA by any Federal or State agency. Selection of this alternative will ensure that diseased animals will continue to infect their cohorts and that brucellosis will continue to circulate in the bison herd. This could potentially result in the spread of the disease to other animals, such as cattle, that could come in contact with infected bison. Spread of brucellosis could potentially affect the current brucellosis-free status of States within the GYA, which could lead to an adverse economic impact to ranchers and others dependent upon the cattle industry for income.

B. Subcutaneous Vaccination of Wild, Free-ranging Bison With Strain 19

Under this alternative, wild, free-ranging bison in the GYA would be vaccinated with Strain 19 vaccine with assistance from APHIS. This option would provide an increased level of resistance to the brucellosis infection and help control the spread within existing bison herds and to other animals.

As with most vaccines, 100% efficacy is not expected. The efficacy of the Strain 19 vaccine in bison is variable, based on documented studies. As demonstrated in studies with Strain 19, some vaccinated animals could develop brucellosis vaccine strain infection as a result of the vaccine. Although only calves and nonpregnant yearlings would be vaccinated, it is important to note that if pregnant female bison are vaccinated, they are potentially subject to abortion as a result of the vaccine. Studies indicate that the rate of abortion following vaccination with Strain 19 in bison is as high as 58% (Davis *et al.*, 1991). In documented studies, vaccination with Strain 19 did not appear to provide adequate protection from later brucellosis infection to bison vaccinated in calfhood. Finally, in some animals, vaccination with Strain 19 causes vaccinated animals to develop antibodies that

may cause the standard serologic tests used in the field to detect brucellosis infection to be positive.

Controlled studies documenting the effects of the Strain 19 vaccine in nontarget animals are lacking; however, years of experience using Strain 19 in cattle, elk, and bison have not resulted in a discernible manifestation of impacts to nontarget species (Cook and Rhyan, 2002, *in* Kreeger, 2002). This is not to say that impacts have not occurred; only that, while not looked for, no obvious problems were noted.

There is no expected opportunity for exposure of the general public to Strain 19. The only potential for human exposure to the Strain 19 vaccine would be from accidental exposure during vaccination procedures. Documented studies demonstrate that the Strain 19 vaccine is pathogenic in humans and can cause undulant fever or allergic reactions in exposed individuals.

C. Subcutaneous Vaccination of Wild, Free-ranging Bison With Strain RB51

Under this alternative, wild, free-ranging bison calves and nonpregnant yearlings in the GYA would be vaccinated with RB51 vaccine. Depending upon its efficacy, over time, vaccination with RB51 is expected to increase the resistance of existing wild, free-ranging bison herds to infection by brucellosis, thus reducing the incidence of brucellosis in wild, free-ranging bison in the GYA. This would reduce the potential threat of infection with brucellosis for GYA cattle and improve the health of wild, free-ranging bison in the GYA.

RB51 is widely recognized as safe for use in bison. Some studies indicate that RB51 does not induce clinical illness in animals and is not transmitted from vaccinates to co-housed nonvaccinates. The lack of any reported adverse reactions in thousands of bison administered the commercial vaccine under field conditions also suggests that RB51 is safe in bison (USDA, APHIS, VS, undated).

RB51 is unlikely to be shed from vaccinated animals. Of 48 vaccinated bison monitored for shedding at regular intervals, only one CFU (colony-forming units) of RB51 was found from one vaginal swab of one bison at 2 weeks after vaccination (USDA, APHIS, VS, undated). Therefore, vaccination of bison calves and nonpregnant yearlings is unlikely to result in contamination of the environment or exposure of nontarget species to the vaccine. Even if exposed, numerous studies have shown that nontarget species are unaffected by

exposure to RB51 (Cook and Rhyan, 2002, *in* Kreeger, 2002). These studies include deer mice, ground squirrels, voles, ravens, various ungulates, coyotes, and black bears. Strain RB51 has been directly shown to be safe in all the nontarget species requiring testing by the GYIBC except no testing has been conducted in wolves. Because wolves are an endangered species, coyotes and domestic dogs are legitimately used as surrogate species for wolves. RB51 has been shown to be safe for both of these species as well.

A further indication that no negative impact is likely to result from the vaccination of calves and nonpregnant yearling bison is the fact that all nontarget species in the GYA that have been exposed to bison and elk also, in all likelihood, have been exposed to the more virulent field strain *Brucella* organisms. To date, there is no documentation of significant problems relating to field strain brucellosis in the GYA except to the elk and bison (and one cattle herd that was exposed to brucellosis-infected elk). Because the RB51 vaccine is a modified and thus less pathogenic form of *Brucella*, this suggests that the RB51 brucellosis vaccine is unlikely to cause detrimental effects to nontarget species (Cook and Rhyan, 2002).

There is no expected opportunity for exposure of the general public to RB51. The only potential for human exposure to the RB51 vaccine would be from accidental exposure during vaccination procedures. The Centers for Disease Control established passive surveillance for accidental inoculation with RB51 to determine if this vaccine was associated with human disease. The study (as cited in USDA, APHIS, VS, undated), which included a small number of exposed people, indicated that both local and systemic adverse events could occur, but that appropriate antibiotic use after exposure should protect against human infection.

IV. Special Considerations

A. Endangered Species

Federally listed endangered and threatened species or their habitats will not be affected by the vaccination of bison. The vaccination of bison was considered in the Biological Assessment prepared for the Joint Bison Management Plan developed and agreed to by Federal agencies for the long-term management of YNP bison. The Biological Assessment, concurred with by the U.S. Fish and Wildlife Service (FWS), concluded that vaccination of bison would have no effect on

federally listed endangered and threatened species. APHIS confirmed with FWS that vaccination of bison with RB51 would have no effect on listed species (Edmundson, 2002).

B. Social Issues

Bison, the largest mammals in the GYA, are strictly vegetarian and graze on grasses and sedges. They are enjoyed by GYA visitors, celebrated by conservationists, and highly revered by many American Indian tribes.

1. American Indian Concerns

Bison are central to the American Indian culture and religious ideologies that represent their spirit and remind American Indians of how their lives were once lived. The InterTribal Bison Cooperative (ITBC) was formed in 1990 to coordinate and assist tribes in returning bison to American Indian lands (ITBC, 2001). Their goal is to establish healthy bison populations on tribal lands in an effort to reestablish hope and help heal the spirit of both the American Indian people and the bison. The ITBC is a tribal organization committed to reestablishing bison to American Indian lands in a manner that promotes cultural enhancement, spiritual revitalization, ecological restoration, and economic development.

In the long term, vaccination of bison will support the goals and efforts of the ITBC by providing a healthier bison population. The vaccination of bison also will contribute to ongoing or future efforts of area land managers to reduce the risk of brucellosis transmission while maintaining wild, free-ranging bison in the GYA.

2. Additional Statutory Considerations

Through cooperation with other agencies, including USDOI's National Park Service and USDA's Forest Service, as well as State wildlife and livestock agencies, APHIS will ensure that the vaccination facilities will not adversely impact cultural or historical sites.

3. Bison Protection Advocates

In addition to the ITBC, animal rights groups, environmental organizations, and individuals advocate the protection of bison in and around the GYA. These groups support the idea of wild, free-ranging bison and are often opposed to any means of controlling or managing the free-ranging bison in the GYA. Some of these advocates believe that if bison are going to survive into the future as a genetically intact species, it is imperative that wild, free-ranging bison herds are allowed to grow and reproduce in a natural environment.

Bison protection advocates observe and document the daily movements of bison outside YNP and endeavor to protect them from the hazing, capturing, and slaughter operations performed by the MDOL and cooperating agencies. Vaccination will contribute to ongoing efforts on the part of area land managers to reduce the risk of brucellosis transmission while permitting healthier wild, free-ranging bison in the GYA. Vaccination will not increase the number of bison being captured, tested, and sent to slaughter.

4. Secondary Impacts

This EA examines the use of RB51 vaccine to subcutaneously inoculate captured and brucellosis-seronegative bison that migrate outside of lands managed by the National Park Service. Activities associated with vaccination of bison are not expected to adversely impact the area ecosystems.

The information available for RB51 vaccination of bison indicates that there would be low adverse risks to animal safety, public health, or the environment. Vaccination is expected to be beneficial to bison and reduce the threat of brucellosis to other nontarget animals and the environment, as well as to humans. Personnel involved in vaccination activities will adhere to safe practices in the administration of the vaccine.

Vaccination activities will not impact winter recreational activities, such as cross-country skiing and snowmobiling, because the vaccination of bison will be conducted in enclosed capture facilities that are located in areas remote to recreational activities.

V. Agencies Contacted

Legal Consultant
Montana Department of Livestock
Helena, MT

Office of the General Counsel
USDA
Washington, DC

Executive Officer
Montana Board of Livestock
Helena, MT

Area Veterinarian in Charge
USDA
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U.S. Department of the Interior
Helena, MT

Wildlife Biologist
Bison Ecology and Management
Yellowstone National Park

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Appendix A. Greater Yellowstone Interagency Brucellosis Committee Protocol for Evaluating Safety and Efficacy of a Wildlife Vaccine against Brucellosis in the Greater Yellowstone Area

The Greater Yellowstone Interagency Brucellosis Committee (GYIBC), formed in 1995, coordinates efforts to eliminate brucellosis from elk and bison in the Greater Yellowstone Area (GYA). The GYIBC's goal is to protect and sustain the existing free-ranging elk and bison populations in the GYA and protect the public interests and economic viability of the livestock industry for the States of Idaho, Montana, and Wyoming. The GYIBC is comprised of the agriculture and wildlife agencies of the States of Idaho, Montana, and Wyoming; the U.S. Department of the Interior's Fish and Wildlife Service and National Park Service; USDA's Forest Service, Animal and Plant Health Inspection Service, and Agricultural Research Service; and the National Biological Service. The members make up the Executive Committee, the Technical Subcommittee, and Information and Education Subcommittee of the GYIBC.

As part of its scope of work, the GYIBC developed general guidance for evaluating the safety and efficacy of a wildlife vaccine against brucellosis in the GYA. The current most likely brucellosis vaccine candidates for use in bison are forms of live *Brucella abortus* bacteria; therefore, criteria regarding the biological safety (i.e., the lack of pathology or other harmful effects) induced by the vaccine have been developed. For domestic livestock, these include ensuring clinical signs of acute disease do no appear after vaccination; bacteria are not present in nasal secretions, saliva, or urine; bacteria do not persist in the bloodstream for more than 3 days; bacteria do not persist in lymph nodes for more than 16 weeks; evidence of humoral or cellular immunity is present 14 days after infection; no inflammation or chronic tissue injury appears; neither placentitis nor abortion occurs in pregnant animals; immunosuppression after 16 weeks does not cause recrudescence; bacteria recovered after 12 weeks growth in the host are genetically identical with the vaccine strain. For free-ranging wildlife, other elements must be evaluated for the administration of live bacteria vaccine. These elements are addressed through a protocol for evaluating safety and efficacy of a wildlife vaccine against brucellosis in the Greater Yellowstone Area, as follows:

Protocol for Evaluating Safety and Efficacy of a Wildlife Vaccine against Brucellosis in the GYA

Adopted by the Greater Yellowstone Interagency Brucellosis Committee,
May 1998

The purpose of this protocol is to establish guidelines for the development and evaluation of new brucellosis vaccines to be used in free-ranging elk *(Cervus elaphus)* and bison *(Bison bison)* inhabiting the Greater Yellowstone Area. This protocol is not intended to evaluate current vaccination programs being applied to these species. The recommendations for the following criteria regarding efficacy and safety are based on the assumption that any brucellosis vaccine evaluated by these criteria would have defined dosage, route of administration, and age restrictions for any application of the vaccine. The vaccine strain will demonstrate stable characteristics following in vitro and in vivo passage. Efficacy evaluations within the prinicipal species should include animals of minimal recommended age, at the minimally recommended dosage and administered in accordance with recommendations. For safety evaluations within the principal species, animals should be of minimal recommended age, at the maximal recommended dosage, and administered in accordance with recommendations. The assumption is also made that the criteria for approval of a vaccine as safe will be the same in both male and female animals in the targeted population. For the purposes of this paper, the definition of a calf will be a bison or elk of less than 12 months of age. Restrictions on use (e.g., sex, age) may be applied without rejection of the vaccine in total. For example, limit use to females because of adverse reactions in males.

Calfhood Vaccination

Safety

To be defined as safe, a vaccine would not have any clinical effects that would increase predation or decrease survivability. However, adverse clinical effects, such as listlessness, anorexia, depression, and arthritis, that are transient and minimal with no long-term effects on survival

may be acceptable. There should be no statistical difference between vaccinates and controls on these factors.

A safe calfhood vaccine will not be shed from a vaccinate prior to parturition. The vaccine strain will not persist to the first calving in 95% or greater of the vaccinated individuals, or persistence of the vaccine strain will not be associated with a significant reduction in survivability (i.e., no pathology) or the reproductive potential of the individual (i.e., repeated fetal loss, infected calves, or decreased fertility). There should be no statistical difference between vaccinates and controls on these factors.

Efficacy

To be defined as efficacious in females, a vaccine must induce statistically greater protection against fetal loss, infected calves, or infection in pregnant vaccinates after experimental challenge when compared to non-vaccinated animals in the same experiment. Infection is defined as either number of colony-forming units (CFU) per gram of tissue and/or number of infected tissues.

Use of model predictions must indicate that the vaccine, when used alone without other management influence, will reduce the prevalence of brucellosis in the targeted wildlife population.

Experiments will need to be conducted to evaluate the duration of immunity of the vaccine but these experiments will not be required for initiation of use of the vaccine if all other safety and efficacy criteria are met. A vaccine should provide long-term immunity and/or be able to be safely boosted during the life of the animal.

Adult Vaccination

Safety

A safe vaccine will not induce significant reductions in survivability or reproductive efficiency as statistically demonstrated in clinical trials.

A safe vaccine will not cause a significant reduction in recruitment in the population of the target species.

Efficacy
A vaccine will be determined to be efficacious if it induces statistically greater protection in vaccinates against fetal loss, infected calves, or infection after experimental challenge when compared to non-vaccinated animals in the same experiment. In addition, modeling must indicate that the vaccine, when used alone without other management influence, will reduce the prevalence of brucellosis in the targeted wildlife population.

Other
A major advantage of any vaccine would be the ability to differentiate vaccinates from animals infected with *Brucella* field strains either by a serologic test or by alternative methods.

Nontarget Species
A vaccine candidate cannot cause deleterious effects on the short-term survivability of representative ungulates, rodents, carnivores or avian species under experimental conditions. Candidate species that should be strongly considered for evaluation include: moose, bighorn sheep, antelope, mule deer, coyotes, wolves, ravens, microtus, peromyscus, and ground squirrels. Other species could be added if scientific data supports their inclusion.

Finding of No Significant Impact for Subcutaneous Vaccination of Wild, Free-ranging Bison in the Greater Yellowstone Area Environmental Assessment, November 2003

The U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Environmental Services (ES) prepared, at the request of Veterinary Services (VS), an environmental assessment (EA) entitled "Subcutaneous Vaccination of Free-ranging Bison in the Greater Yellowstone Area." The EA was prepared to fulfill the intent and purposes of complying with the public involvement principle relevant to the Council on Environmental Quality Regulations for Implementing the Procedural Provisions of the National Environmental Policy Act (40 Code of Federal Regulations (CFR) 1500–1508) because of the public interest in the wild, free-ranging bison of the Greater Yellowstone Area (GYA). The EA, incorporated by reference, is available through the Internet at http://www.aphis.usda.gov/ppd/es/vsdocs.html and from the following office:

U.S. Department of Agriculture
Animal and Plant Health Inspection Service
Veterinary Services, NAHPS
4700 River Road, Unit 43
Riverdale, MD 20737–1231

The EA analyzed the alternatives of (1) No Action, (2) Subcutaneous Vaccination of Wild, Free-ranging Bison with Strain 19, and (3) Subcutaneous Vaccination of Wild, Free-ranging Bison with Strain RB51. Based on the information presented in the EA, I have selected Alternative 3, Subcutaneous Vaccination of Wild, Free-ranging Bison with Strain RB51, as the preferred alternative because of its ability to assist in achieving objectives set forth in the Interagency Bison Management Plan (IBMP) and the Record of Decision issued for the IBMP in December 2000. The use of Strain RB51 will not adversely impact endangered and threatened species, other wildlife, human health and safety, and the environment. In addition, the study will not infringe upon the cultural rights of American Indians. I based this finding on the following information.

Data presented in the EA reveals that there are no significant environmental effects associated with the subcutaneous vaccination of wild, free-ranging bison in the GYA using RB51 vaccine. Indeed, the EA basically confirms that the proposal fits within the categorical exclusion classification contained in the agency's National Environmental Policy Act implementing procedures (7 CFR 372.5(c)(ii)(A)).

Studies of the vaccines described in the EA indicate that RB51 is superior to Strain 19 in the following respects: it does not produce antibodies that interfere with serologic tests, as does Strain 19; it produces less pathogenic effects in the target animal than Strain 19; and it does not cause as many abortions in pregnant cattle and bison as Strain 19. Inadvertent inoculation of

personnel involved in vaccination is not known to cause undulant fever and can be treated with appropriate antibiotic use.

The use of RB51 vaccine is not likely to adversely impact the environment in that it is rarely shed from vaccinated animals, and no adverse impacts to nontarget species have been identified from studies of the vaccine, including potential impacts to predators. During the NEPA process for the IBMP, the FWS indicated that bison vaccination would have "no effect" to endangered and threatened species. That determination of no effect was discussed and confirmed with FWS relative to the use of RB51 vaccine for vaccination of bison in the GYA. Therefore, no impact is expected to federally or State-listed endangered and threatened species. Furthermore, the location of capture facilities will not impact historic or archeological resources.

In consideration of the foregoing findings of the EA, I have determined that subcutaneous vaccination with Strain RB51 of wild, free-ranging bison of the GYA will not significantly impact human health or the environment.

This finding and the underlying EA will be made available to the public through public notice in the Federal Register and posting on the Internet, as mentioned above. These documents will also be distributed to individuals and groups who have previously expressed an interest in the subject matter. Comments are welcome.

/s/ 11/12/03

W. Ron DeHaven
Deputy Administrator, Veterinary Services
Animal and Plant Health Inspection Service

Date